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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/639,948	08/12/2003	Rajat Sethi	12695.6USD6	6989
23552	7590	06/07/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			JONES, DWAYNE C	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/639,948

Applicant(s)

SETHI ET AL.

Examiner

Dwayne C. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24MAR2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 6-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 6-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/24/6</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1 and 6-16 are pending.
2. Claims 1 and 6-16 are rejected.

### ***Response to Arguments***

3. Applicant's arguments with respect to claims 1 and 6-16 have been considered but are moot in view of the new ground(s) of rejection.

### ***Information Disclosure Statement***

4. The information disclosure statement of March 24, 2006 (2 sheets) has been reviewed and considered, see enclosed copy of PTO FORM 1449.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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6. Claims 1 and 6-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 14-16 of U.S. Patent No. 6,043,259 in view of Hardman, J. G., Editor-in-chief of Goodman & Gilman's THE PHARMACOLOGICAL BASIS OF THERAPEUTICS, 9<sup>TH</sup> Edition, 1996. Dhalla et al. of U.S. Patent No. 6,043,259 teach of treating cardiovascular disorders, namely hypertrophy, with the administration of pyridoxal-5'-phosphate, pyridoxal, and pyridoxamine, (see claims 19-21). Hardman, J. G. teaches of that congestive heart failure is one of the most common causes of death and disability in the industrialized nations. Hardman, J. G. also states that before initiating drug therapy for heart failure, it is important to eliminate or mitigate other potentially reversible cause of cardiac dysfunction, such as myocardial ischemia, cardiac arrhythmias, and hypertension, as well as other causes, and Hardman, J. G. further teaches that primary hypertrophic cardiomyopathy often leads to thickened, poorly compliant ventricular walls with small ventricular volumes. In addition, Hardman, J. G. discloses that treatment must be tailored to the underlying pathophysiological process in an individual patient. One of the most common causes of heart failure is due to advanced coronary atherosclerosis. Hardman, J. G. also discloses that it is common practice in the art to interventional, pharmacological, and dietary therapies designed to slow the progression of or reverse coronary atherosclerosis should be initiated concurrently with the drug therapy (see page 809). In fact, it is common practice to administer the following well known pharmaceuticals for the treatment of heart failure and congestive heart failure, such as diuretics, (see pages 820-824), vasodilators (see pages (824-836), in particular, calcium

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channel blocker (see pages 829 and 831), angiotensin converting enzyme (ACE) inhibitors, (see pages 825-827 and 830),  $\beta$ -adrenergic receptor antagonists (see pages 831-835). Hardman, J. G. also teaches of the antioxidants of vitamin C (see pages 1568-1571) and vitamin E (see pages 1573 and 1585-1588). In fact, Hardman, J. G. provide explicit motivation to use antioxidants, such as vitamins A, C, and E in protection against cardiovascular, including congestive heart failure, and malignant diseases and that nutrient deficiency increases the risk for disease (see page 1573). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Clearly, one having ordinary skill in the art would have been motivated from the prior art teachings to simply combine already known pharmaceutical agents, such as angiotensin converting enzyme (ACE) inhibitors, diuretics, and vitamins, along with in order to treat the very same cardiovascular disorder of hypertrophy.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (571) 272-0578. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, and Fridays from 8:30 am to 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, may be reached at (571) 272-0718. The official fax No. for correspondence is (571)-273-8300.

Also, please note that U.S. patents and U.S. patent application publications are no longer supplied with Office actions. Accordingly, the cited U.S. patents and patent application publications are available for download via the Office's PAIR, see <http://pair-direct.uspto.gov>. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 1-866-217-9197 (toll free).

  
DWAYNE JONES  
PRIMARY EXAMINER  
Tech. Ctr. 1614  
June 5, 2006